

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center—WO66-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

SEP - 1 2009

**Re: 510(k) Number K090156**  
**Isolyser SMS Traditional 510(k)**  
**WCM Waste and Compliance Management, Inc.**  
**Carlsbad, CA 92011**

**510(k) Summary**

**Owner of Device**

WCM Waste & Compliance Management, Inc.  
6054 Corte Del Cedro  
Carlsbad, CA 92009-1514

**Contact**

Sara Beth Watson  
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**Date Prepared**

August 13, 2009

**Name of Device**

Common Name: Sharps Container  
Proprietary Name: Isolyser SMS; Sharps Room System (SRS) 800; Sharps Management System (SMS) 2400; Sharps Management System (SMS) 4000; and Sharps Management System (SMS) 10000.

Establishment Registration Number: 2032810 (2008)

Classification Name: Accessory to hypodermic single lumen needles

Regulation: 880.5570

Classification: Class II

Product Code: MMK and/or FMI

Panel: General Hospital

### **Device Uses and Description**

The Isolyser SMS is a disposable over-the-counter sharps container that is intended for the safe and effective disposal of used medical sharps. The SMS is marketed in four (4) different models: (1) Sharps Room System (SRS) 800, .98 liters; (2) Sharps Management System (SMS) 2400, 3.3 liters; (3) Sharps Management System (SMS) 4000, 5.97 liters; and (4) Sharps Management System (SMS) 10000, 10.47 liters. The SMS containers are marketed for use in the offices, exam, and patient rooms of small quantity healthcare providers such as medical doctors, dentists, veterinarians, and laboratories. The SMS sharps containers are not intended for reuse.

The SMS's container is stable, closable, puncture resistant, and leak-proof on the sides and bottom. Used medical sharps are placed vertically into the opening on the top of the container and dropped into an acrylamide solution that is contained inside the container. Once the SMS container has been filled with used medical sharps, users: add the provided catalyst packages to the acrylamide solution inside the container; securely place the lid onto the container; shake the container for ten (10) seconds; and allow the polymer to form overnight. Once the polymer has formed, the entire SMS container, including its contents, may be disposed in a user's ordinary trash in most states. It is the user's responsibility to dispose of the SMS container in accordance with Federal, State and Local regulations. The overall design and specifications for the Isolyser SMS meet OSHA Bloodborne Pathogens Standard as well as the American Society for Testing and Materials Puncture Resistance Standard F2132-01(2008). All SMS containers have BIOHAZARD warning labels clearly visible with lettering in contrasting color and are affixed by adhesives to the sides of the SMS container.

### **Predicate Devices**

The Isolyser SMS sharps containers are substantially equivalent in intended use, function, and basic composition to the sharps containers approved under 510(k) number K943626. The Isolyser SMS sharps containers have similar technological characteristics to the sharps containers approved in 510(k) K943626; the containers are identical in size, composition, and design. Further, both the Isolyser SMS and the sharps containers approved in 510(k) K943626 contain acrylamide solutions that, once the provided catalysts have been added, create a polymer that encapsulates used medical sharps. Once polymerization is complete, the entire SMS container, including its contents, may be disposed in the user's ordinary trash in most states if acceptable under Federal, State and Local regulations.

### **Conclusion**

The Isolyser SMS is substantially equivalent to the predicate devices based on the descriptive data, compliance with standards, and indications for use.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

WCM Waste & Compliance Management, Incorporated  
C/O Ms. Sara Beth Watson  
Steptoe & Johnson L.L.P.  
1330 Connecticut Avenue, N.W.  
Washington, D.C. 20036

SEP - 1 2009

Re: K090156

Trade/Device Name: ISOLYSER SMS Sharps Container, Models: Sharps Room System (SRS) 800; Sharps Management System (SMS) 2400; Sharp Management System (SMS) 4000; and Sharps Management System (SMS) 1000

Regulation Number: 21 CFR 880. 5570

Regulation Name: Hypodermic Single Lumen Needle

Regulatory Class: II

Product Code: FMI

Dated: August 13, 2009

Received: August 14, 2009

Dear Ms. Watson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address  
<http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Anthony D. Watson Jr.*

Susan Runner, D.D.S., M.A.  
Acting Division Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

**510(k) Number (if known):** K090156

**Device Name:** Isolyser SMS Sharps Containers, including models: Sharps Room System (SRS) 800; Sharps Management System (SMS) 2400; Sharps Management System (SMS) 4000; and Sharps Management System (SMS) 10000.

**Indications For Use:** The Isolyser Sharps Management System (SMS) is a disposable over-the-counter sharps container that is intended for the safe and effective disposal of used medical sharps. The SMS sharps containers are designed to safely and securely contain used medical sharps prior to removal and subsequent disposal. The SMS is marketed in four (4) different models: (1) Sharps Room System (SRS) 800, .98 liters; (2) Sharps Management System (SMS) 2400, 3.3 liters; (3) Sharps Management System (SMS) 4000, 5.97 liters; and (4) Sharps Management System (SMS) 10000, 10.47 liters. Each SMS model includes a water-based acrylamide solution that, when mixed with the provided catalysts, creates a polymer that encapsulates used medical sharps. Once the polymer has formed, the entire SMS container, including its contents, may be disposed in a user's ordinary trash in most states. It is the user's responsibility to dispose of the SMS container in accordance with Federal, State and Local regulations. The SRS 800, SMS 2400, SMS 4000, SMS 10000 are intended for use by small quantity health care providers such as dentists, medical doctors, veterinarians, and laboratories. The SMS sharps containers are not intended for reuse.

**Prescription Use** \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

**Over-The-Counter Use**  \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Shelia P Murphy, DO  
(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K090156